Policy Number	107.000
Policy Title	INSTITUTIONAL REVIEW BOARD (IRB)
Responsible Officer	PROVOST
Responsible Office	Office of the Provost
Summary	The following policy outlines the purpose of the Institutional Review Board (IRB), including the IRB procedures concerning human participants.
Definitions	**Human Subject –** A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (45 CFR 46.102.e) **IRB** – An institutional review board established in accord with and for the purposes expressed in this policy. (45 CFR 46.102.g) **IRB Approval** – The determination of the IRB that research has been reviewed and may be conducted within the constraints set for the by the IRB and by other institutional and federal requirements. (45 CFR 46.102.h) **Minimal Risk** -- Risk is judged minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102.j) **Research –** A systematic investigation designed to develop or contribute to generalizable knowledge. (45 CFR 46.102.l)
Approving Body	Academic Council; Administrative Council
Approval Date	Aca C (06.12.2020); Admin C (06.19.2020)
Last Revision	
Re-evaluation Date	Fall 2024
Departmental Impact	All academic areas

Failure to follow the following policy may result in disciplinary action, including termination of employment.

Policy Statement: Projects proposed by faculty, students, and administrators involving the use of humans as participants in research must be submitted for institutional review and approval. All individuals submitting applications or interacting with human participants must obtain a certification demonstrating their knowledge of research ethics. ALL RESEARCH PROJECTS MUST RECEIVE APPROVAL FROM THE INSTITUTIONAL REVIEW BOARD (IRB) BEFORE THE STUDY CAN TAKE PLACE.

Rationale CIU seeks to conform to the criteria of the federal Office for Human Research Protections (OHRP) which provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research. CIU is concerned with the protection of the rights and welfare of human subjects in all research and class projects. This concern includes the protection of rights to privacy, the need for informed consent, protection of confidentiality of data, and protection against physical, psychological, social, legal, or spiritual risks. IRB reviews are intended to minimize discomforts and/or risks to the participants and to assure that researchers/investigators comply with Federal regulations.

Policy Procedures

1. IRB Authority

The IRB is that mechanism established by CIU to exercise its responsibility to protect the rights and welfare of human subjects in various categories of research in any way related to the institution. Its jurisdiction includes approval, disapproval, modification, ongoing review, verification of changes, suspension and/or termination of approval. The goal of IRB review is to facilitate research, while at the same time protecting human subjects. IRB approval signifies only that the rights and welfare of human subjects have been appropriately protected.

2. IRB Committee

The IRB Committee is comprised of 12 members appointed by the Provost for a three-year term. The Provost will designate

the Chairperson. The Committee will consist of at least 10 members who have terminal degrees and who have competence in the area of research. As far as possible, the members should be diverse as to gender, subject education, and cultural backgrounds. One member should represent the community and have no CIU affiliation other than possibly being an alumnus. IRB members may not participate in reviewing an approval request in which they have a conflict of interest although such members may provide any information requested by the IRB. (45 CFR 46.107) Each IRB member will have obtained a certificate of training for ethics in research.

3. IRB Purpose

The purposes of the IRB are to (1) ensure the protection of the rights of all human subjects involved in research projects carried out by CIU faculty, staff, or students; (2) ensure that research conducted by CIU faculty, staff, or students meets the standards required by government agencies; and (3) protect the researcher/investigator in cases where ethical issues are pertinent. The function of the IRB Committee is not censorial; therefore, methodological issues will not be evaluated so long as they do not impact risk and ethical concerns.

In cases where research involves minimal risk to human subjects (Exempt and Expedited Levels of IRB Review), the Committee's function is primarily administrative. Exempt protocols will be reviewed by the Chairman, who will confirm that the exempt designation is appropriate and file it in the IRB records. Expedited protocols may be reviewed by the Chairman or a designated IRB committee member. In cases where research involves more than minimal risk, the IRB Chair will convene the full board to review the protocol. These meetings may be conducted in person, online, or through e-mail exchange. The decision to approve the protocol must be unanimous.

4. IRB Operations

The IRB will meet three times per year. The dates for these meetings will be posted as part of the official academic calendar. Proposals (applies to full-board reviews only) to be considered at a meeting must be received by the Chairperson at least two weeks prior to a stated meeting. The IRB will establish communication guidelines that ensure prompt notification of IRB actions, including the use of IRB software as appropriate. The Committee will maintain the IRB Website and IRB Guidebook with further details and forms, as well as keep adequate documentation of IRB activities with appropriate records for at least three years after completion of the research.

5. IRB General Criteria

The IRB must determine: (45 CFR 46.111)

- That any risks to subjects are minimized.
- That risks to subjects are reasonable in relation to anticipated benefits.
- That the selection of subjects is equitable and just.
- That informed consent will be sought and appropriately documented or waived.
- That the research plan makes adequate provision for the monitoring of data to insure subject safety.
- That the privacy of subjects and the confidentiality of data are adequately protected;
- That any participating institutions/sites have indicated appropriate approval of participation.
- That no University student be required to participate as a subject in any research project as a course requirement without appropriate informed consent. Courses that involve a human subject research requirement must indicate that participation as a subject is always voluntary and an alternative to participation must be offered.
- That subjects be safeguarded from coercion or undue influence.
- That investigators do not attempt to recruit subjects in their own classes.

6. Human Subject Research (HSR) Training:

Any faculty, staff, or student seeking approval of a research project must supply evidence of having met certification in CITI Program's training module: Human Subjects Research (HSR) for Social-Behavioral-Educational Researchers. Completion of this module is automatically documented from CITI Program to the researcher's record in Axiom Mentor. Alternate HSR training may be accepted with the approval of the IRB Chairman. This will be manually entered into the Axiom Mentor system.

7. IRB Proposal

The researcher/investigator has the responsibility to submit the research protocol using the appropriate IRB application (Exempt, Expedited, or Full-Board) to the IRB at least two weeks before a Committee meeting. Each IRB application includes

a statement, written and signed by the principal investigator and primary faculty advisor, mentor, or project director which conforms to provisions below and which describes projects from the point of view of the protections afforded human subjects. It is the primary means, along with survey forms and informed consent documents, by which the investigator informs the IRB about a project which the Committee is required to review. The Committee will not review a research protocol unless a written IRB application has been submitted electronically on the Axiom Mentor system. The research protocol, when approved by the Committee, becomes part of the agreement between the Committee and the investigator about the way in which a project will be conducted.

The research protocol should contain the following information: (45 CFR 46.116)

- A summary of the nature and purpose of the research activity.
- A full description of the human subjects proposed to be involved, their characteristics, the total number anticipated, and how they will be selected
- A full description of how the subjects will be used in the activity.
- A full description and assessment of the potential benefits and risks, if any, to the individual human subjects, and/or to society in general as a result of the activity. Risks may be physical, psychological, spiritual, or social. Assess the likelihood, severity, and duration of such risks.
- A description of the means taken to minimize risks, including the means by which the subject's personal privacy is to be protected and the confidentiality of the information obtained from the subject maintained.
- A description of the procedures to be used in obtaining and documenting the prior informed consent of the subject, including a statement made that participation is voluntary with an explanation of whom to contact for answers to pertinent questions. Written consent forms are required for research done at CIU.
- If questionnaires or interview schedules are to be used in the project, a copy of each should be attached to the Research Protocol section of Axiom Mentor.
- Any special or unusual circumstances regarding the activity which the principal investigator believes could be relevant to the Committee's decision in reviewing the project should be described or included.
- In order to have an IRB Application reviewed, the principal investigator or co-principal investigators, other investigators, and research assistants must have current documentation of CITI Program's training module: Human Subjects Research (HSR) for Social-Behavioral-Educational Researchers. See above: 6. Human Subjects Research Training for further details.

The IRB Application must be signed by 1) the principal researcher/investigator and 2) the primary faculty advisor, dissertation chair, mentor, or project director. Once approved, the IRB Chairman will communicate to the researcher and advisor/supervisor by the IRB Chairperson via e-mail. This indicates acceptance of the responsibility by each for assuring that the activity will be conducted in accordance with ethical principles concerning the protection of human subjects. Contact information regarding the investigator should be included. If the proposal is for a thesis, doctoral project, or dissertation, the names of the Committee members should be included. For Full-Board Reviews, the IRB Application, along with copies of questionnaires, interview schedules, informed consent documents, training certificate, and other supporting materials, should be submitted to the Chairperson of the IRB Committee at least two weeks before the scheduled IRB meeting.

Further details and forms are found on the IRB Axiom Mentor site and in the IRB Guidebook.

Hyperlinks
www.ciu.edu/policy